

Notice of Allowability

Application No.

10/661,784

Applicant(s)

DONATE ET AL.

Examiner

Anand U. Desai, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to January 30, 2006.
2. ☒ The allowed claim(s) is/are 1-13 and 40-43.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

1. This office action is in response to Amendment filed on January 30, 2006. Claims 1-13 are currently pending and are under examination. Claims 14-42 have been previously withdrawn.

Withdrawal of Rejections

2. The new matter rejection of claims 1-3 under 35 U.S.C. 112, first paragraph is withdrawn.

3. The rejection of claims 1-13 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Shmuel Livnat on February 14, 2006.

Examiner's amendment to the claims:

1. (Currently amended) An isolated anti-angiogenic polypeptide that is:
 - (a) a variant of native HK-D3 (SEQ ID NO: 1) designated HK-D3v, which has the amino acid sequence SEQ ID NO: 3, or

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- (b) ~~an N-terminal addition variant of native HK-D3 (SEQ ID NO: 1), which a~~
variant of native HK-D3 (SEQ ID NO: 1) that has an N-terminal addition
and has the sequence SEQ ID NO: 2,

which polypeptide ~~or variant~~ has at least 20% of the activity of native HK-D3 (SEQ ID NO: 1) in inhibiting angiogenesis, endothelial cell proliferation or endothelial tube formation in an *in vitro* or *in vivo* bioassay.

2. (Currently amended) The isolated polypeptide of claim 1, which has the sequence SEQ ID NO: 3.

3. (Currently amended) A diagnostically ~~or therapeutically~~ labeled anti-angiogenic polypeptide comprising the ~~the~~ [[a]] polypeptide ~~or variant~~ according to claim 1 to which ~~[[i]]~~ is conjugated a detectable diagnostic label ~~or (ii) is bound a therapeutically active moiety.~~

8. (Currently amended) An anti-angiogenic pharmaceutical composition comprising:

- (a) an anti-angiogenic effective amount of the polypeptide ~~or variant~~ of claim 1, and
(b) a pharmaceutically acceptable carrier.

10. (Currently amended) A therapeutic anti-angiogenic pharmaceutical composition comprising:

- (a) an effective amount of the polypeptide of claim 43 ~~[[3]]~~ to which the therapeutically active moiety is bound directly or indirectly; and
(b) a therapeutically acceptable carrier.

14.-39. (Cancelled).

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40. (Currently amended) An affinity matrix ligand ~~useful~~ for binding to or isolating an HK-D3-binding molecule or cells expressing the binding molecule, comprising the polypeptide ~~or variant~~ of claim 1 immobilized to a solid support or carrier.

41. (Currently amended) A method for isolating a HK-D3-binding molecule from a complex mixture comprising:

- (a) contacting the mixture with an affinity matrix ligand of claim 40;
- (b) allowing material in the mixture to bind to the matrix ligand;
- (c) removing unbound material from the matrix ligand; and
- (d) eluting the bound HK-D3-binding molecule,
thereby isolating said HK-D3-binding molecule.

42. (Currently amended) A method for isolating or enriching cells expressing a HK-D3-binding site or receptor from a cell mixture, comprising

- (a) contacting the cell mixture with the affinity matrix ligand of claim 40;
- (b) allowing any cells expressing the binding site or receptor to bind to the affinity matrix ligand;
- (c) separating cells bound to the affinity matrix ligand from unbound cells; and
- (d) removing the bound cells from the affinity matrix ligand,
thereby isolating or enriching the HK-D3 binding site-expressing cells.

43. (New) A therapeutically labeled anti-angiogenic polypeptide comprising a polypeptide according to claim 1 to which is bound a therapeutically active moiety.

Allowable Subject Matter

5. Claims 1-13, and 40-43 are allowable.

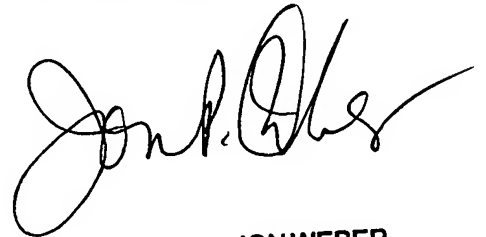
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 17, 2006



JON WEBER
SUPERVISORY PATENT EXAMINER